EXHIBIT A

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February 14, 2019

VIA EMAIL - rebecca.falk@usdoj.gov

Rebecca A. Falk Assistant United States Attorney United States Attorney's Office Northern District of California 450 Golden Gate Avenue, 9th Floor San Francisco, California, 94102

Re: SEC v. Balwani; Case No. 5:18-cv-01603-EJD

Balwani Subpoena to CMS

Dear Ms. Falk,

This letter sets forth our response on behalf of Mr. Balwani to the February 11, 2019 email to my colleagues from Lindsay Turner, an attorney with the Office of the General Counsel at the U.S. Department of Human Services (HHS). This letter also addresses and responds to the issues discussed during the February 12, 2019, meet and confer conference call attended by you, Ms. Turner, and my colleagues, Ben Byer and Amanda McDowell. As you know, our subpoena to CMS, an agency of the United States Government that is part of HHS and represented by the Department of Justice, was served many months ago in September 2018. In all of this time, we received only one very small production from CMS, on January 3, 2019, consisting of 43 documents. The January 2019 production was incomplete and a large volume of responsive documents has not even been searched for yet, let alone produced. During the government's investigation and based on requests from the investigating agencies, CMS collected and supplied about 250,000 pages of documents.

We can no longer tolerate the delay in producing the materials that we have requested as part of Mr. Balwani's defense. As outlined below, please let us know no later than February 20th: (1) whether the government will commit to a date certain for production of the subpoenaed documents, including the internal CMS communications requested by Mr. Balwani below, and (2) whether the government will commit to a date certain for production of a privilege log for any CMS documents it withholds under a claim of privilege, as required by Ninth Circuit authority. Without a firm commitment on these issues, or if the date certain is unreasonable given the passage of time and needs of the case, we will have to seek appropriate relief from the Court.

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We appreciate that the government is finally working to respond meaningfully to Mr. Balwani's subpoena, but this work has only come after a significant delay of over five months that has already prejudiced Mr. Balwani's ability to prepare his defense and identify CMS witnesses that he may need to depose in this case. To be clear, the CMS documents that were produced to Mr. Balwani by the SEC and DOJ were documents that were collected for the government's investigation into Theranos before this case was initiated. We did not ask you to reproduce those documents, and the government and its agency did not have to do any work gathering or producing these documents in response to Mr. Balwani's subpoena.

We learned for the first time this week that the government now plans to construct a database to load and review additional responsive CMS documents. We understand from the February 12 meet and confer call that the government anticipates that this database could take several weeks to construct, after which time additional documents will have to be loaded, CMS personnel will have to be given access to the database, and only then can the government begin reviewing additional documents that may be produced. You informed my colleagues on the February 12 call that the government can give us no time frame or date certain for when this process will be completed. Especially in view of the lengthy delay since we served the subpoena, we cannot be confident that weeks will not turn into many months.

We are also troubled by the fact that this endeavor is just now being planned. Through our lengthy meet and confer process, we have tried to ease any burden facing the government, expedite this process, and avoid unnecessary Court involvement. Indeed, Mr. Balwani has made substantial concessions during this process, such as conducting research and providing CMS with names of third parties and CMS custodians, working to narrow time frames, and responding at length to each of CMS's requests for our legal position on various issues. We will also forego for the time being our demand for production of documents relating to Medicare reimbursement of Theranos blood testing, although we reserve the right to renew our request for these materials should the need arise based on further developments in discovery.

The below sets forth our requests, pared down to the maximum extent possible in view of the issues in the case. If the government is unable to agree to these requests, we are prepared to bring these issues before the Court seeking an order directing the government to comply with its obligations under Rule 45 in a timely manner.

Internal CMS Communications (Requests 1, 3-8, 16)

The government has agreed to search for internal CMS communications from November 20, 2015 – December 31, 2016. As we have discussed, this time frame omits key events relating to CMS that are relevant to Mr. Balwani's defense. For instance, CMS or its agent inspected Theranos in December 2013, made an inspection request in June 2015, conducted another

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inspection in September 2015, obviously discussed internally the findings of that inspection, and came back for a third inspection in November 2015. We are willing at this time to forego collection and production of documents created after July 7, 2016, so you may omit the period after that date from your collection efforts. We reserve the right to renew our request for these materials should the need arise based on further developments in discovery.

The government must therefore search for and produce internal communications between **September 1, 2013 to July 7, 2016**, in order to capture the entire period when communications leading up to, during, and in the aftermath of the audits and inspections are likely to have occurred. We have explained the relevance of these communications in extensive detail in prior communications, including Ms. McDowell's February 5th email, but the bottom line is that CMS was the primary regulator and inspection authority for Theranos's labs, and the complaint is filled with allegations that Mr. Balwani misrepresented the nature and capabilities of the laboratory-developed tests that CMS was regulating and inspecting.

Regarding custodians, it is the government's responsibility to identify custodians who were involved with the regulatory and inspection issues for Theranos to capture all responsive documents. Please let us know the custodians from which you will be collecting documents, but those custodians should include all custodians that may have responsive documents and at least the following individuals who it appears were reviewing Theranos's labs based on the documentary evidence we have seen so far: Sarah Bennett, Karen Dyer, Karen Fuller, Penny Keller, Gary Yamamoto, Patrick Conway, Mandy Cohen, Megan O'Reilly, Debbra Hattery, Danielle Andres, Thomas Hamilton, Jan Tarantino, Judy Yost, Lisa Watkins, Maria Martino, Kate Goodrich, Jean Moody-Williams, Shari Ling, and Renee Henry.

Privilege Log

The government has informed us that it has "no position" on whether it plans to produce a privilege log for any internal communications it will withhold on the grounds that the material is covered by the deliberative process privilege. Any assertion of the deliberative process privilege would be inappropriate here—however, at the very least CMS would be required to produce a privilege log of withheld documents as required by established Ninth Circuit authority. *Pac. Fisheries, Inc. v. United States*, 539 F.3d 1143, 1148 (9th Cir. 2008). We therefore are seeking a commitment from CMS to log any documents that are withheld under a claim of privilege.

Date Certain

As we mentioned, Mr. Balwani cannot identify the CMS witnesses he may need to depose without the documents, including the internal communications, and his ability to defend this case is substantially prejudiced with every passing day that the government continues to delay production.

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Accordingly, please let us know no later than <u>February 20th</u> the government's position on the following:

- Will CMS commit to producing the responsive documents identified in this letter, including the internal communications from the custodians and dates ranges discussed above by a date certain?
- Will CMS commit to producing a privilege log for all responsive documents withheld on the grounds of the deliberative process privilege by a date certain?

Remaining Requests

Subject to the discussion above concerning the need for the government to commit to a date certain, your agreement to identify custodians from which documents will be collected, and commitment to a privilege log, we are agreeable to Ms. Turner's approach to the collection and production of documents responsive to the remaining requests of Mr. Balwani's subpoena. Of course, we reserve the right to seek additional materials should the need arise based on further developments in discovery

We look forward to hearing from you by February 20, 2019.

Best,

Davis Wright Tremaine LLP

Jeffrey B. Coopersmith

cc Lindsay Turner (via email – <u>lindsay.turner@hhs.gov</u>)

Marc D. Katz (via email - katzm@sec.gov)

Susan F. LaMarca (via email - lamarcas@sec.gov)